

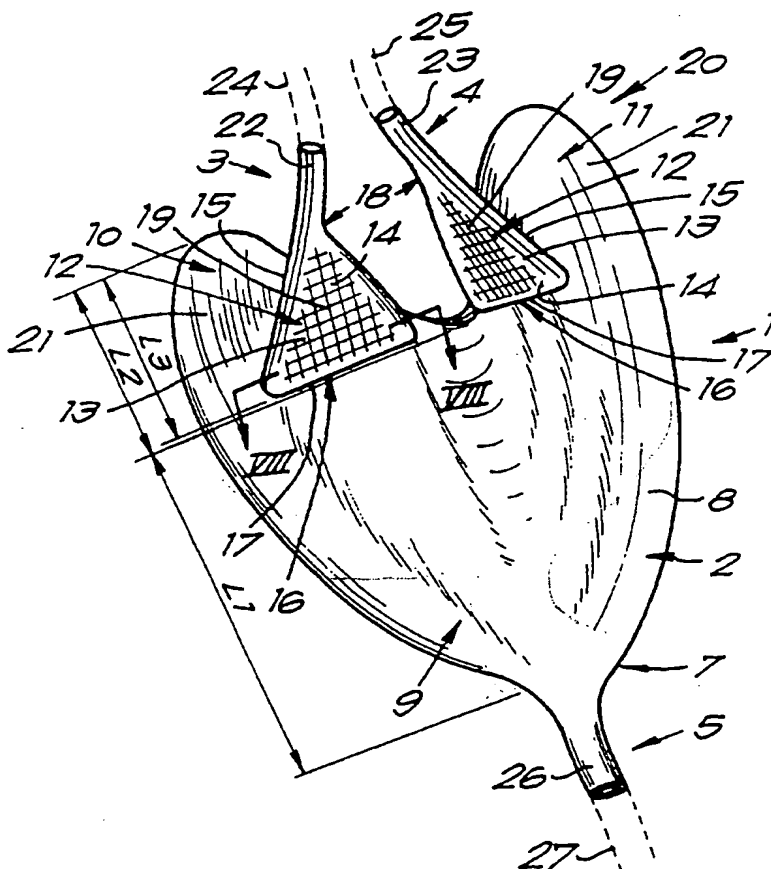
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(21) International Application Number: PCT/BE94/00074 (22) International Filing Date: 26 October 1994 (26.10.94) (30) Priority Data: 9301202 29 October 1993 (29.10.93) BE (71) Applicant (for all designated States except US): SURE, BESLOTEN VENNOOTSCHAP MET BEPERKTE AANSPRAKELIJKHEID [BE/BE]; Dongenblok 15, B-2431 Veerle-Laakdal (BE). (72) Inventors; and (75) Inventors/Applicants (for US only): LEONARD, André [BE/BE]; Dorpsstraat 18, B-2590 Berlaar (BE). BRUSSELEERS, Paul [BE/BE]; Dongenblok 15, B-2431 Veerle-Laakdal (BE). (74) Agent: DONNE, Eddy; Bureau M.F.J. Bockstael N.V., Arenbergstraat 13, B-2000 Antwerpen (BE).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ). Published With international search report. In English translation (filed in Dutch).	

(54) Title: BLADDER PROSTHESIS

(57) Abstract

Bladder prosthesis, consisting of a liquid container (2) with at least one entry (3-4) and at least one exit (5), characterized in that the liquid container (2) has a shape which is anatomically adapted to the shape of the pelvis.



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Bladder prosthesis.

5 The present invention concerns a bladder prosthesis.

It is known that a total cystectomy, i.e. the removal of the bladder, is a severe and mutilating operation for the patient which has a serious impact on the patient's self-
10 image in the negative sense.

Traditionally, this operation is carried out in case of certain forms of bladder cancer. There are also numerous other symptoms whereby such an operation may be necessary
15 or appropriate, such as neuronal complaints, for example resulting from injuries of the spinal cord, multiple sclerosis, etc.; inflammatory incursions, for example tuberculosis, interstitial cystitis, post radio therapy; gynaecological complaints; as well as disorders related
20 to other fields.

These operations automatically lead to the problem of the urinary bypassing. Traditionally, both ureters are implanted in an isolated small bowel segment, of which
25 one end is provided as urostoma on the skin.

In order to avoid a stoma with all the aesthetic and psychological damages it entails, different procedures have already been suggested to make a reservoir out of
30 intestinal loops. In this way, orthotopical bladder reconstructions have been made with a good continence and with preservation of the integrity of the higher tract.

An alternative consists in the implantation of the

ureters in the large bowel, whether or not in combination with the formation of a reservoir. However, these so-called "pouches" require much experience and lengthy training of the patient and moreover the operation is not free of any risk. In any case, one must reckon with a lengthy operation.

It is known that the surgical complexity of the above-mentioned operations still entails a high post-surgical morbidity and mortality.

The present invention aims to solve the above-mentioned problem by making use of an implantable bladder prosthesis. In particular, the invention concerns a bladder prosthesis with optimum characteristics during and after the implantation.

To this end the invention concerns a bladder prosthesis, consisting of a liquid container with at least one entry and at least one exit, characterized in that the liquid container has a shape which is anatomically adapted to the shape of the pelvis.

More in particular, the prosthesis preferably has a shape which makes it possible for it to be situated convex over the sigmoid.

Further, the bladder prosthesis according to the invention preferably also has a front side which is formed according to the shape of the pubis.

The liquid container will preferably consist of at least one virtual basic space, as well as of at least one virtual side space extending sideways upward as of the

basic space and connected onto the latter.

According to the most preferred embodiment, the bladder prosthesis according to the invention has two side spaces
5 connected symmetrically onto the basic space, which extend to the left and to the right respectively of the basic space.

According to a characteristic of the invention, which can
10 be whether or not combined with the above-described characteristics, each of the entries of the bladder prosthesis is provided with anti-reflux means, whereby these anti-reflux means mainly consist of a chamber,
15 whether or not virtual, in which the above-mentioned entry is provided on the one hand, and whereby this chamber is connected to the above-mentioned liquid container on the other hand.

Thanks to the use of the anti-reflux means, a cysto-
20 ureteral reflux can be avoided, as a result of which infections in the ureters are excluded and a pressure build-up in the actual bladder becomes possible, which is necessary to generate the required stimuli which indicate that the bladder is filled. The use of anti-reflux means
25 in the form of chambers, which are preferably but not necessarily virtual, is among other things advantageous in that it is not necessary to provide mechanical valves or such, which may fail.

30 According to the most preferred embodiment, each of the anti-reflux means consist of chambers formed of two parallel walls which are designed such that, after the implant, they are situated against or almost against one another. Such anti-reflux means are advantageous in that

they require little space thanks to their flatness, in that they cannot fail and in that they offer an optimal anti-reflux action.

5 Moreover, the invention also aims, according to its most preferred embodiments, a bladder prosthesis which also has the following characteristics:

- entire bio-compatibility;
- a sufficiently large capacity to fulfil such a
10 reservoir function;
- easily implantable, with the required flexibility to meet all possible clinical post-surgical conditions;
- technically easily suturable, both on the urethral
15 stumb and on the ureters;
- a low pressure in between lumens so as to safeguard the higher urinary tract;
- prevention in the long term of infections and stone formation.

20

Another aim of the invention is to provide a prosthetic model of a bladder which is designed to make an insitu reconstruction of the urinary tract possible while retaining the normal voiding and continence.

25

In order to better explain the characteristics of the invention, the following preferred embodiments are described as an example only without being limitative in any way, with reference to the accompanying drawings,

30

where:

figure 1 represents a bladder prosthesis according to the invention;

figure 2 represents the bladder prosthesis of figure

1 after the implantation;
figures 3 to 7 represent sections according to lines
III-III to VII-VII from figure 2 to a larger scale;
figure 8 shows a section according to line VIII-VIII
5 from figure 1 to a larger scale;
figure 9 is a schematic representation of the
pressing together of certain parts of the bladder
prosthesis after the implantation;
figure 10 shows yet another bladder prosthesis
10 according to the invention;
figure 11 shows a view to a larger scale of the part
which is indicated in figure 10 with F11;
figure 12 shows yet another variant of the bladder
prosthesis according to the invention.

15

As represented figure 1, the bladder prosthesis 1 mainly
consists of a liquid container 2 with at least one, but
in this embodiment two entries 3 and 4, and an exit 5.

20 According to the invention, the liquid container 2 as
represented in figures 1 to 7 has a shape which is
anatomically adapted to the shape of the human pelvis,
i.e.

25 which is made according to the topographic anatomic
proportions of the pelvis.

As is also represented, the bladder prosthesis 1
preferably also has a shape which makes it possible for
it to be situated convex over the sigmoid.

30

Moreover, it preferably has a front side 6 which is
formed according to the shape of the pubis.

The liquid container 2 may have a rounded apical angle 7

at the bottom directed towards the back upon which the exit 5 is provided.

Further, the liquid container 2 is preferably made like a bladder, in other words a container with a flexible wall 8. In particular, the liquid container 2 is preferably made such that it functions as a virtual space.

10 The liquid container 2 is made of bio-compatible synthetic material, it is preferably thin-walled and consists of very flexible material.

Preferably, the wall 8 mainly consists of thin-walled silicone sheets or another synthetic material. By these "silicone sheets" is meant that the wall 8 is built up of different layers which are formed by means of several successive immersions in a silicone bath, whereby the silicone is cured at each stage. The final product is in fact a single silicone wall. The use of thin-walled silicone sheets results in the creation of a so-called "flat-shaped bladder" whose sheets touch when the bladder is empty. In vivo, there will be at the most a thin film of urine between the sheets.

25 The use of a thin-walled liquid container 2 offers the advantage that the intra-abdominal pressure is sufficient to empty this container without a considerable residue staying behind. The use of a flexible and thin-walled material for the wall 8 also has for a result that the bladder prosthesis 1, if necessary, will easily adjust to the surface and configuration of the pelvis which it has to occupy, irrespective of the shape, sex or age of the patient.

According to a special characteristic, in order to optimize the foldability, the bladder prosthesis 1 is evenly thin-walled, whereby it is whether or not provided with a rough outer surface, as will be described
5 hereafter.

Basically, in order to make it function optimally, the space which is surrounded by the liquid container 2 is so to say composed of at least one virtual basic space 9, as
10 well as of at least one, but as represented in figures 1 to 7 preferably two virtual side spaces 10 and 11 extending sideways upward as of the basic space 9 and connected onto the latter.

15 For clarity's sake, the lengths L1 and L2 are represented in figure 1 which indicate the distances over which the basic space 9 and the side spaces 10 and 11 respectively extend.

20 The two side spaces 10 and 11 are preferably situated in a symmetrical manner on both sides of the basic space 9.

As represented in the sections of figures 3, 4 and 5, the side spaces 10-11 may narrow towards the top, whereas
25 they gradually merge into the basic space 9 towards the bottom.

The parts of the wall 8 which surround the side spaces 10-11 are preferably designed such that each of the side
30 spaces 10-11 can be pressed flat together, which implies that the opposite wall parts can be put together, without any folds arising, over their entire or almost entire surface.

According to a characteristic of the present invention, which can be whether or not combined with one or several of the characteristics described in detail above, every entry 3-4 is provided with anti-reflux means 12 which
5 mainly consist of a - whether or not virtual - chamber 13 in which the above-mentioned entry 3, 4 respectively, is provided on the one hand, and whereby this chamber 13 is connected to the above-mentioned liquid container 2 on the other hand.

10

As long as it is unloaded, every chamber 13 provides a free passage, meaning that no valves or such are mounted therein.

15

As represented in the figures 1 to 9, the anti-reflux means 12 preferably consist of chambers 13 which are formed of two mainly parallel wall parts 14-15 which are designed such that they will be situated flat against one another or almost against one another after the
20 implantation.

25

In order to obtain an optimal anti-reflux action, the chambers 13 of the anti-reflux means 12 can be connected onto the liquid container 2 via a constriction 16.

25

Said constriction 16 may consist of a groove, as represented in detail in figure 8.

30

The above-mentioned chambers 13 may have the shape of triangular wings, whereby one side 17 of the thus formed triangle is connected onto the liquid container 2 and whereby the accompanying entry, 3 or 4 respectively, is provided on the angular point 18 opposite said side 17.

The wall, in particular the above-mentioned wall parts 14 and 15, of the chambers 13 of the anti-reflux means 12 is preferably provided with a reinforcement, such as a cast-in synthetic reinforcement or texture 19.

5

The above-mentioned anti-reflux means 12 preferably open into the liquid container 2 at a distance L3 under the top end 20 of this liquid container 2, but at least at a distance of for example five centimetres from the exit 5.

10

In the case of an embodiment with side spaces 10-11, as represented in the figures 1 to 9, the anti-reflux means 12 preferably open into these side spaces 10-11, in particular in their lower half. They are hereby provided on the sides 21 of the side spaces 10-11 directed towards the inside.

15

Basically, the anti-reflux means 12 will be designed as ileal wings.

20

Finally, it is clear that the entries 3 and 4 are preferably equipped with connecting pieces 22 and 23 for the ureters 24 and 25.

25

In order to provide for an optimal anastomose with the ureters 24 and 25, the above-mentioned connecting pieces 22 and 23 preferably consist of fine or coarse synthetic material. Preferably, use is hereby made of a material which is fit for a good incorporation and epithelialisation, for example a material made of or based on PTFE (polytetrafluoroethylene) or Dacron.

30

The connecting pieces 22-23 can be cast onto the wall material of the chambers 13 without any problems, fused

to it or attached to it according to another method.

In an analogous way, a connecting piece 26 can be provided at the exit 5, preferably also made of any of the above-mentioned materials. It can be made such that an attachment to the urethra 27 becomes possible. As a result, a normal depletion of the bladder prosthesis 1 becomes possible, as the sphincter can work normally in this case.

10

As described above, the whole preferably forms a bi-valvular system which can fold entirely together when empty.

15 The working of the bladder prosthesis from figures 1 to 9 is mainly as follows: during the implantation, the ureters 24 and 25 are connected onto the entries 3 and 4 via the connecting pieces 22 and 23 and the urethra 27 via the connecting piece 26.

20

The fact that the anti-reflux means 12 are situated low on the inside offers the prime advantage that almost the entire length of the ureters 24-25 can be preserved, so that they remain available should other operations be required afterwards, such as the replacement of the bladder prosthesis by another one.

25

The fact that the shape of the bladder prosthesis 1 is adapted to the shape of the pelvis and the use of the above-mentioned side spaces 10-11 offers the advantage that these side spaces 10-11, as represented in figure 9, are situated between the abdominal wall 28 and the large bowel 29, so that a pressure is always available which makes it possible to empty the bladder prosthesis

30

optimally. As the wall parts which surround the side spaces 10 and 11 are entirely flattened, the formation of kidney stones in these side spaces 10 and 11 is practically excluded.

5

As is further represented in figure 9, the specific shape offers the advantage that the above-mentioned wall parts 14 and 15 are also pressed flat together, which promotes the good working of the anti-reflux means 12. The wall parts 14 and 15 which are pressed together make it possible for the urine from the ureters 24 and 25 to trickle in between, but the urine cannot flow back. The flowing back is also prevented by means of the constriction 16.

15

Although the shape of the bladder prosthesis 1 which is represented in figures 1 to 9 gives the best results, it is clear that the invention is not restricted to this embodiment.

20

Indeed, the invention also concerns other shapes of bladder prostheses 1 which are adapted to the shape of the pelvis.

25

Moreover, it is clear that the anti-reflux means 12 as represented in the invention can also be used for other bladder prostheses while still remaining within the scope of the invention.

30

Figure 10 shows a variant in which each of the anti-reflux means 12 mainly consists of a preferably bladder-shaped chamber 13 onto which the ureter in question, 24 and 25 respectively, is connected directly or indirectly, whereby this chamber 13 is also connected to the above-

mentioned liquid container 2 via a constriction 16. This also offers the advantage that no mechanical valves or such, which may fail, need to be provided.

5 Such bladder-shaped chambers 13 also offer the advantage that they function as an ileal element. This means that urine from the ureters 24 and 25, which as is known is supplied drop by drop to the bladder, is collected in the chambers 13 and can go from there through the
10 constrictions 16 into the liquid container 2 without any problems, but that the urine collected in this container, thanks to the presence of the constrictions 16, and thanks to the shape of the prosthesis resulting from the presence of the chambers 13, can hardly or not at all
15 flow back into these chambers 13 and thus into the ureters 24 and 25.

In the embodiment represented in figure 10, the chambers 13 are situated to the left and to the right of the top
20 side, but it is clear that they can also open lower into the liquid container 2 as in the embodiment of figures 1 to 9.

When expanded, the liquid container 2 in this case has a
25 mainly rounded triangular section, whereby the apical angle is situated in the centre at the bottom, where the exit 5 is also situated.

The shape of the bladder prosthesis 1 which is
30 represented in figure 10 has for a result that the prosthesis folds together when it is emptied, as indicated by means of the arrows A. This shape offers the advantage that the bladder prosthesis 1 so to say rests on the pelvis and thus is optimally supported.

It is clear that the entries 3-4 and the exit 5 can be provided with the above-mentioned connecting pieces 22-23-26 in an analogous manner.

5 It should be noted that the walls of the chambers 13 are preferably made in one piece with the wall 8 of the liquid container 2, in the first as well as in the second embodiment, which results in a very simple construction which weighs little and is ideal for an implantation.

10

As represented in figure 11, the wall 8 of the liquid container 2, and possibly also of the chambers 13, may be provided with a course outer surface 30, in particular a carved surface. This offers the advantage that the
15 bladder prosthesis 1, due to the movements of the patient, rubs against the surrounding tissues, which strongly reduces capsule formation due to calcification. It is clear, however, that the inner surface 31, is preferably smooth, in order to avoid that residues stay
20 behind in unevennesses and in order to make sure that the liquid container 2 can entirely fold together when being emptied.

It is clear that the invention also concerns a bladder
25 prosthesis 1 with only one entry 3 or 4. It is indeed possible for the ureters 24 and 25 to be linked, so that only one end of a ureter is coupled to the bladder prosthesis 1.

30 According to yet another possibility of the invention, as represented in figure 12, a connecting piece 32 can be provided which makes it possible for both the ureters 24 and 25 to be connected onto one entry 33. Preferably, use is made to this end of a T-shaped connecting piece 32

made of the same material as the connecting pieces 22 and 23. It is clear that the liquid container 2 in this case merely has one entry 33, with the accompanying anti-reflux means 12, whereby the latter preferably consist of
5 a chamber 13 as mentioned above. Moreover, all characteristics mentioned in the description of the embodiment of figure 10 also apply to the embodiment of figure 12.

10 It is clear that if, for example for oncological reasons, also the urethra must be removed, the prosthesis can also be used to create an aesthetic, so-called continent urostoma with a minimum of morbidity, whereby the appropriate discharge means are then provided at the exit
15 5.

The present invention is by no means limited to the embodiments given by way of example and represented in the accompanying drawings; on the contrary, such a
20 bladder prosthesis can be made in all sorts of variants while still remaining within the scope of the invention.

Claims.

- 5 1. Bladder prosthesis, consisting of a liquid container (2) with at least one entry (3-4) and at least one exit (5), characterized in that the liquid container (2) has a shape which is anatomically adapted to the shape of the pelvis.
- 10 2. Bladder prosthesis according to claim 1, characterized in that the prosthesis (1) has a shape which makes it possible for it to be situated convex over the sigmoid.
- 15 3. Bladder prosthesis according to claim 1 or 2, characterized in that it has a front side (6) which is formed according to the shape of the pubis.
- 20 4. Bladder prosthesis according to any of the above claims, characterized in that the liquid container (2) consists of at least one virtual basic space (9), as well as of at least one virtual side space (10-11) extending sideways upward as of the basic space (9) and connected onto the latter.
- 25 5. Bladder prosthesis according to claim 4, characterized in that it has two side spaces (10-11) connected symmetrically onto the basic space (9), which extend to the left and to the right respectively of the basic space
- 30 (9).
6. Bladder prosthesis according to claim 4 or 5, characterized in that the side space, the side spaces (10-11) respectively, narrow towards the top.

7. Bladder prosthesis according to claim 4, 5 or 6, characterized in that the side space, the side spaces (10-11) respectively, have wall parts which can be pressed flat against one another.

5

8. Bladder prosthesis according to any of the above claims, characterized in that each entry (3-4) is provided with anti-reflux means (12), and in that these anti-reflux means (12) mainly consist of a chamber (13),
10 whether or not virtual, in which the above-mentioned entry (3-4) is provided on the one hand, and whereby this chamber (13) is connected to the above-mentioned liquid container (2) on the other hand.

15

9. Bladder prosthesis consisting of a liquid container (2) with at least one entry (3-4) and at least one exit (5), whereby each entry (3-4) is provided with anti-reflux means (12), characterized in that these anti-reflux means (12) mainly consist of a chamber (13),
20 whether or not virtual, in which the above-mentioned entry (3-4) is provided on the one hand, and whereby this chamber (13) is connected to the above-mentioned liquid container (2) on the other hand.

25

10. Bladder prosthesis according to claim 8 or 9, characterized in that the chambers (13) of the anti-reflux means (12) are connected onto the liquid container (2) via a constriction (16).

30

11. Bladder prosthesis according to claim 8, 9 or 10, characterized in that the anti-reflux means (12) each have a chamber (13) with two parallel wall parts (14-15) which are designed such that, after the implant, they are situated against or almost against one another.

12. Bladder prosthesis according to claim 11, characterized in that the above-mentioned chambers (13) open into the liquid container (2) via a groove.

5 13. Bladder prosthesis according to claim 12, characterized in that the above-mentioned chambers (13) have the shape of triangular wings, whereby one side (17) of the thus formed triangle is connected onto the liquid container (2) and whereby the accompanying entry (3-4) is
10 provided on the angular point (18) opposite said side (17).

14. Bladder prosthesis according to any of claims 8 to 13, characterized in that the wall of the chambers (13)
15 of the anti-reflux means (12) is provided with a reinforcement.

15. Bladder prosthesis according to any of claims 8 to 14, characterized in that the chambers (13) provide a
20 free passage.

16. Bladder prosthesis according to any of claims 8 to 15, characterized in that the anti-reflux means (12) open into the liquid container (2) under the top end (20) of
25 this liquid container (2), but at least at five centimetres above the exit (5).

17. Bladder prosthesis according to claims 4 and 16, characterized in that the anti-reflux means (12) open
30 into the lower half of the side space, the side spaces 10-11 respectively.

18. Bladder prosthesis according to claims 4 and any of claims 8 to 17, characterized in that the anti-reflux

means (12) are connected onto the side (21) of the side space (10-11) in question directed towards the inside.

19. Bladder prosthesis according to any of claims 8 to 5 18, characterized in that the chambers (13) of the anti-reflux means (12) are designed as ileal wings.

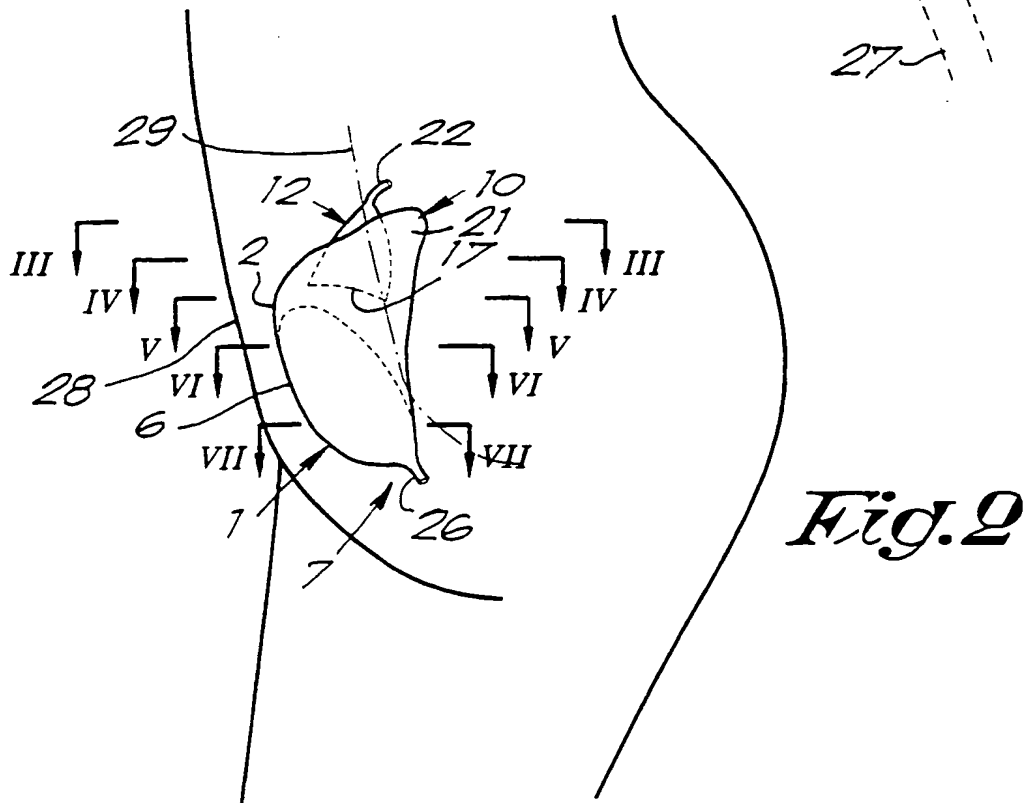
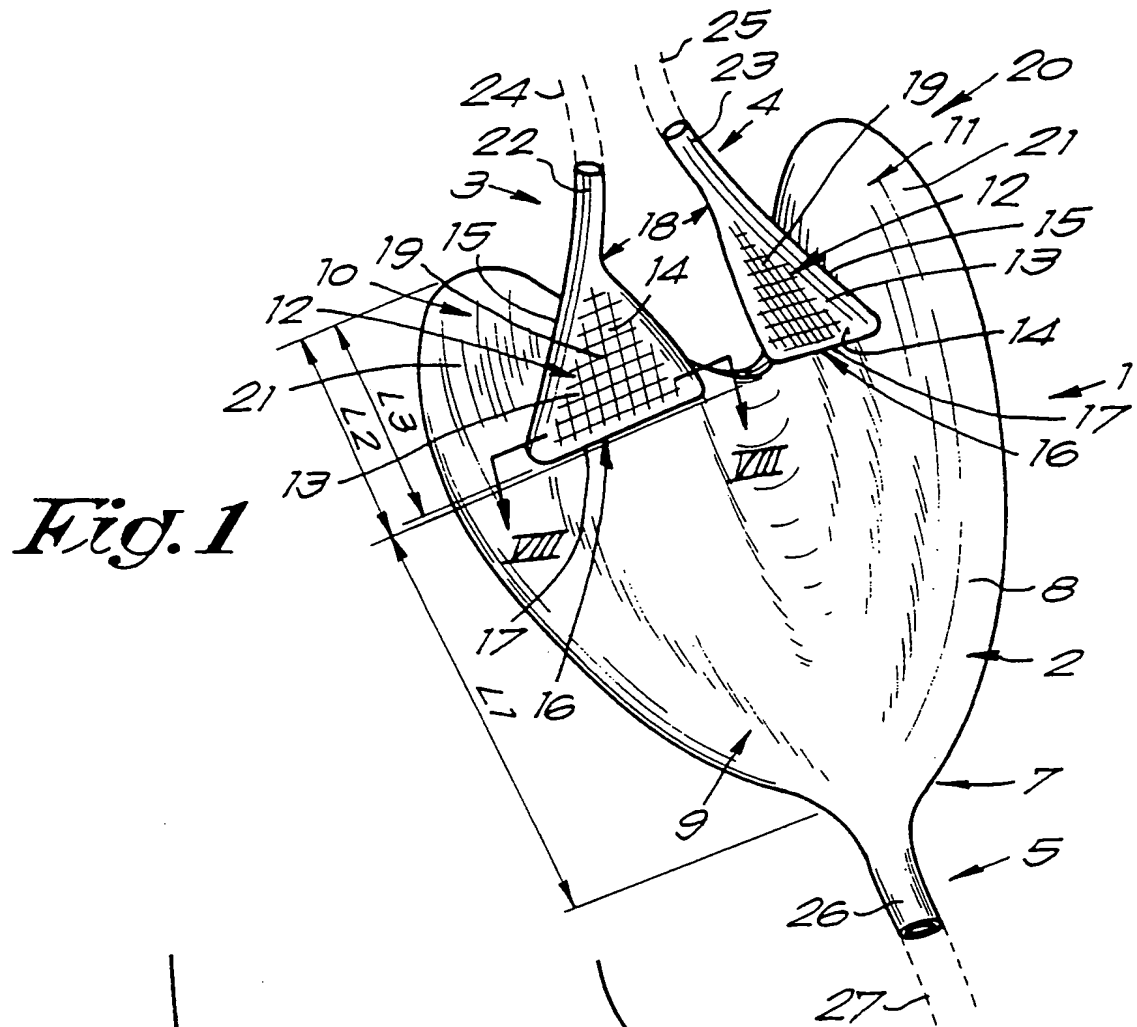
20. Bladder prosthesis according to any of the above claims, characterized in that the liquid container (2) 10 has an apical angle (7) at the bottom directed towards the back upon which the exit (5) is provided.

21. Bladder prosthesis according to any of the above claims, characterized in that the liquid container (2) 15 is evenly thin-walled and whether or not provided with a rough outer surface (30).

22. Bladder prosthesis according to any of the above claims, characterized in that the whole forms a bi- 20 valvular system which can fold entirely together when empty.

23. Bladder prosthesis according to any of the above claims, characterized in that it has an anatomical shape 25 as represented in the accompanying figures 1 to 7.

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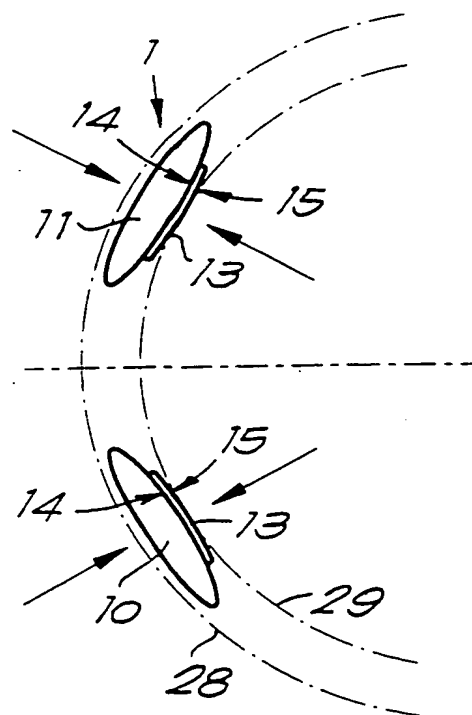
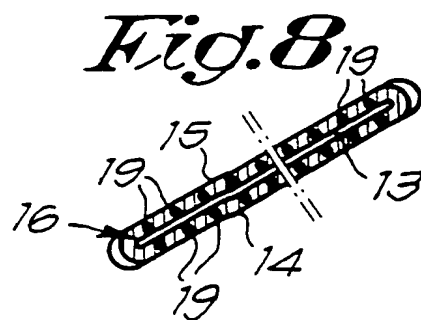
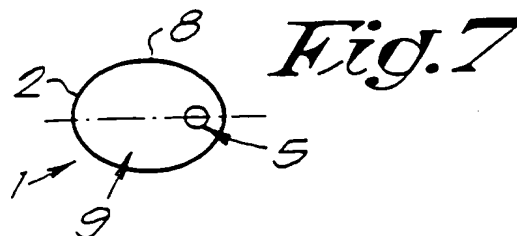
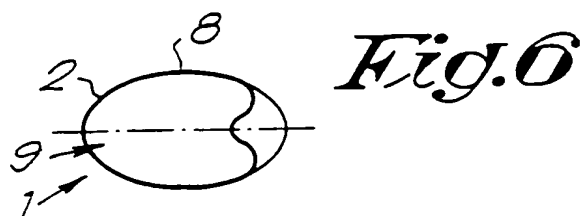
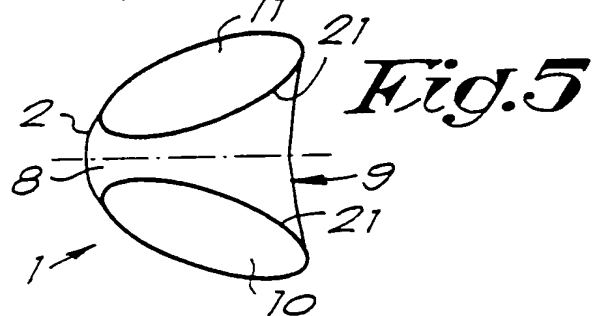
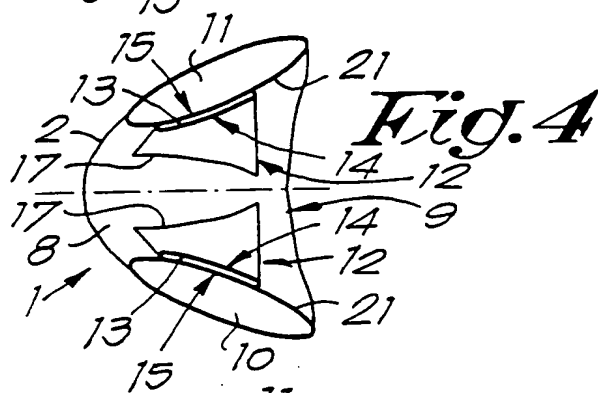
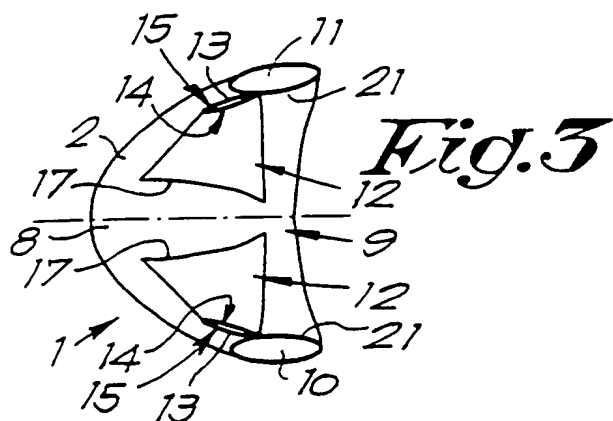
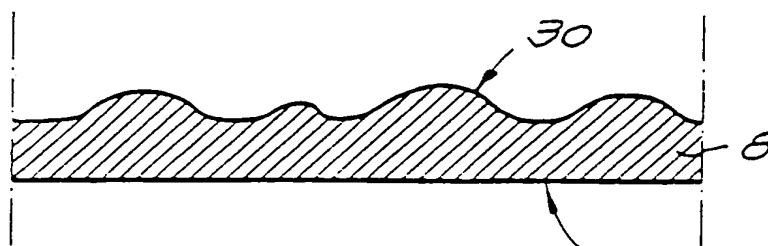
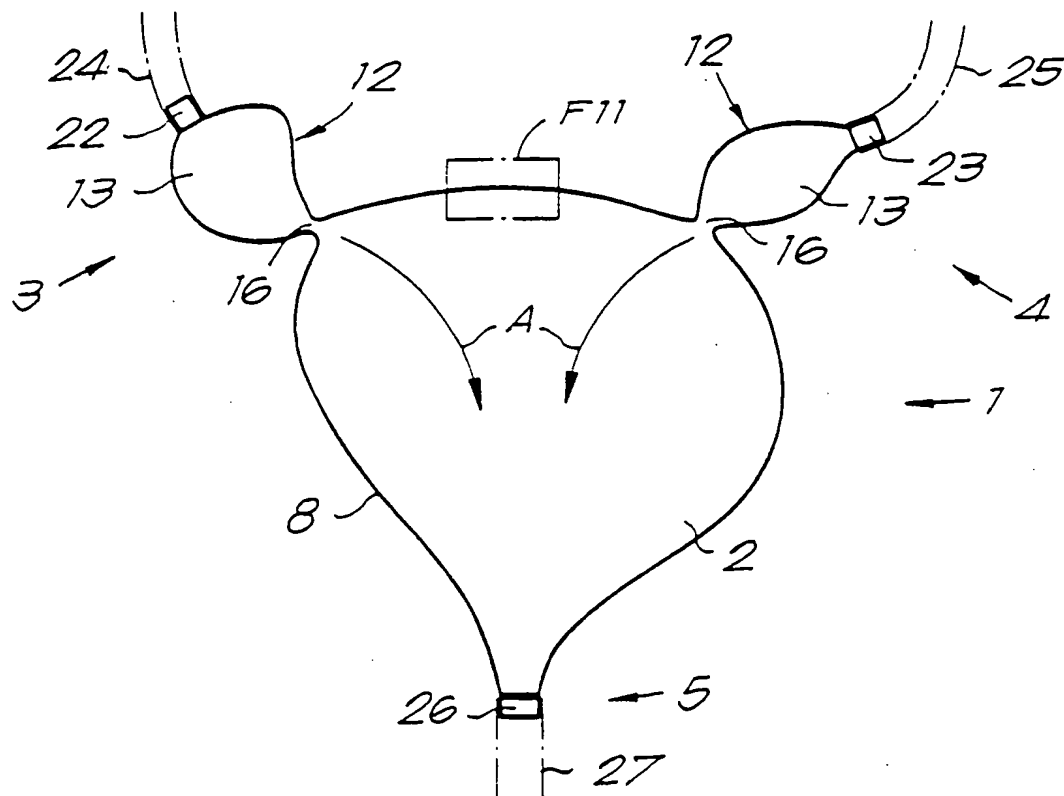


Fig.10*Fig.11*

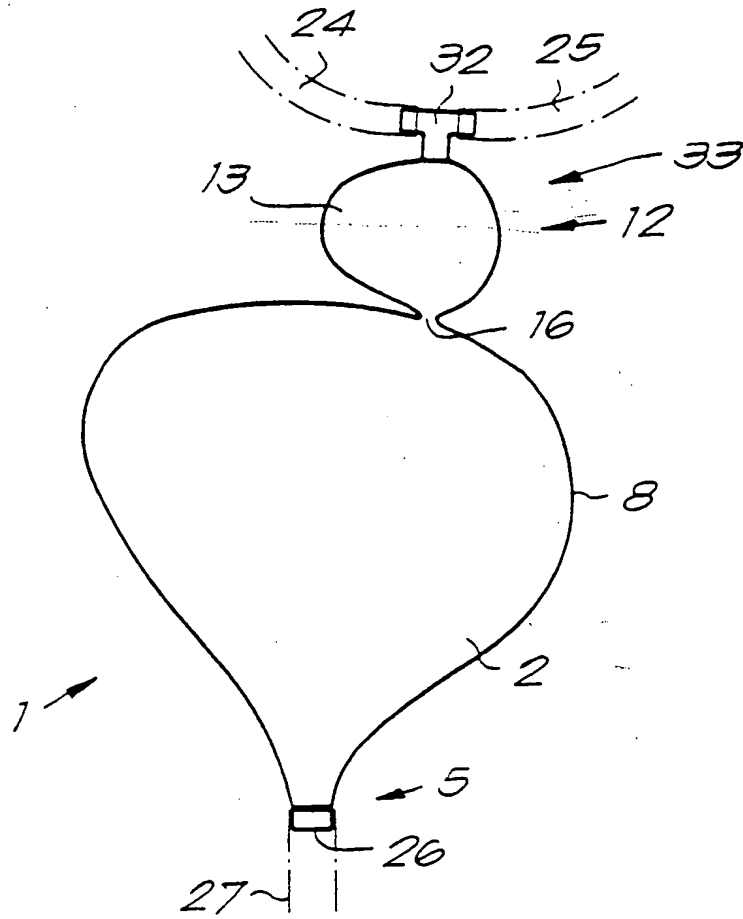


Fig. 12

INTERNATIONAL SEARCH REPORT

Inter. Application No

PCT/SE 94/00074

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	NL,A,7 416 695 (RHÔNE-POULENC) 1 July 1975 see the whole document ---	1-3,21
X	EP,A,0 393 714 (GRIFFITH) 24 October 1990 see claim 1; figures 3,8 ---	1-3
A	FR,A,2 347 031 (ANVAR) 4 November 1977 see page 5, line 3-27; figure 4 ---	1,8-11, 16-18
A	US,A,4 044 401 (GUISET) 30 August 1977 see abstract; figure 1 ---	1
A	WO,A,93 16659 (BARRETT) 2 September 1993 see claim 1; figure 1 -----	1,8-11

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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